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| 09/675,020 | 09/28/2000 | Robert S. Matson | 2014-181 | 7650 |

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EXAMINER

DAVIS, DEBORAH A

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/675,020

Applicant(s)

MATSON ET AL.

Examiner

Deborah A. Davis

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12-3-04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25,31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the Office Action mailed on September 21, 2004 has been acknowledged. Currently, claims 1-25 and 31-32 are pending. Claims 1 and 22 is currently amended and claim 26 through 30 are cancelled.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-2, 4-5, 6-15, 19, 22 and 31-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Moring et al (USP#6,159,368).

Moring et al anticipates the instant claims by disclosing an assembly for a microarray assay device (see Figure 2). The microplate has a plurality of discrete array formation areas each formed of flexible material (col. 14, lines 1-28). Moring et al discloses filter elements that form the bottom of the microplate wells made of material

Art Unit: 1641

that lacks rigidity (col. 14, lines 24-28). Barriers are formed between the array formation areas (see Figure 2). Moring et al discloses a vacuum fixture defining a top surface and an interior chamber connectable to a vacuum source (col. 22, lines 5-13) with a plurality of orifices connected to the interior chamber and opening at the top surface corresponding to the array formation areas when the microplate is mounted on the top surface of the vacuum fixture (col. 22, lines 17-21). Moring et al discloses apertures (orifices) that are extended through the surface of the microplate (see Figure 3, #28) that corresponds to array formation areas. The microplate is located on top of the vacuum chamber (see Figure 2, #24). Barriers such as filter elements are formed for flexible material (col. 17, lines 25-27). The microplate comprises a support plate, a flat substrate formed of the flexible material (col. 14, lines 29-34) over the support plate (Figure 2, #24) and a gasket defining a plurality of holes over the substrate and gasket contains an array formation area (see Figure 2, #44, #32) as recited in claim 6. The microplate has a rigid frame attached to the flexible material (Figure 2, #38) as recited in claim 7. Alternatively, well can be formed in a plurality of strips arranged side by side within a frame designed to hold strips (col. 12, lines 14-31) as recited in claim 8. Moring et al discloses a plurality of biorecognition materials in the microplate array (col. 30, lines 30-34) as recited in claims 9-12. Moring et al discloses a cover plate that contains a nodule (cap) for each well (col. 28, lines 1-5) as recited in claim 19. The microplate has a tray (plates) that is formed of flexible material using conventional means of injection molding (col. 11, lines 55-68).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moring et al in view of Mathus et al (USP#5,858,309).

The teachings of Moring et al are set forth above and differ from the instant claims in not pointing out the material thickness, height, in the microplate and flexural modulus; hardness and specific temperature as recited in claim 18.

However, Mathus et al teaches microplates and methods for manufacturing microplates. This microplate is designed to allow UV radiation to pass through the bottom of the wells (See abstract). In the detailed description of the invention, a microplate with a material thickness of 7.5mils is used to obtain the desired wavelength (col. 4, lines 55-65).

It would have been obvious to one of ordinary skill in the art to vary the thickness in the microplate of Moring et al as taught by Mathus et al to allow UV radiation to pass through the bottom of the wells as to obtain the desired wavelength. With respect to claim 18, it would have been further obvious to one of ordinary skill in the art to vary temperature, hardness and flexibility in microplate assemblies because they are routine optimizations that are almost always determined in material fabrication. Unless the

Art Unit: 1641

result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been obvious for one of ordinary skill in the art to employ these modifications as a means of optimizing the devices provided by the art. With respect to the barriers having a height of less than 4mm is considered a matter of design choice. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 20-21 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moring et al in view of Mohan et al (USP# 5,888,830).

The teachings of Moring et al are set forth above and differ from the instant claims in not teaching such limitations as a lid that has a plurality of caps with inlet/outlet ports, a temperature control element and a vacuum fixture.

However, Mohan et al teaches a capping plate with a plurality of caps that corresponds to an array area and seals the reaction vessel. Each cap has access to an inlet and outlet port and the microplate assembly has a temperature control element (See Figure 1 and 1A). The microplate assembly has a vacuum fixture on the surface of the interior chamber (See Figure 1). A cleavage section that has a chamber

Art Unit: 1641

containing a plurality of vial ports, each holding separate vials with inlet and outlet ports for connecting the chamber to a vacuum supply (col. 2, lines 55-65). The temperature control element can be used to heat or cool fluid that circulates through channels in the plate (col. 13, lines 1-7). The microplate assembly also provides for a silicon heating pad that is sandwiched between the top heater block and the bottom heater block and is connected by leads to a heater control (See Figure 1) which maintains the desired heat level (col. 12, lines 59-63). Such a system would provide an improved apparatus for performing multiple chemical reactions on a solid support in a parallel fashion in a simple and easy manner (col. 1, lines 52-64).

It would have been obvious to one of ordinary skill in the art to incorporate the capping plate of Mohan et al into the microplate of Moring et al to seal the reaction vessel. The vacuum fixture taught by Mohan et al is also obvious for connecting the chamber to a vacuum supply to assist in the flow of fluid. It would have been further obvious to incorporate a heater control element to maintain a desired heat level since such a heating element is usually required for chemical reactions. One of ordinary skill in the art would have also been motivated to add the additional features taught by Mohan et al into the microplate assembly of Moring et al in order to provide an improved apparatus for performing multiple chemical reactions on a solid support in a parallel fashion in a simple and easy manner.

8. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moring et al in view of Stylli et al (USP#5,985,214).

Art Unit: 1641

The teachings of Moring et al are set forth above and differ from the instant claims in failing to teach a peristaltic pump.

However, Stylli et al teaches in his present invention systems and methods that utilize automated and integratable workstations for identifying chemicals having useful activity (See abstract). When live cells are being dispensed, it may be necessary to provide re-circulation of the cell culture through a fluid system in order to prevent adhesion or pooling of the cells, which can be accomplished by a peristaltic pump (col. 59, lines 20-32):

It would have been obvious to one of ordinary skill in the art to modify the microplate of Moring et al to include a peristaltic pump in as taught by Stylli et al to provide re-circulation of the cell culture that would prevent adhesion or pooling of the cells.

Response to Arguments

9. Applicant argues that the reference of Moring cannot anticipate claim 1 because Moring fails to teach that each orifice is connected directly to both the top surface and the interior chamber, wherein each of the orifices is directly below the assay formation areas. Applicant asserts that Moring orifices are located between each microfiltration well and directs examiner attention to Moring, column 22, lines 17-21 and Figures 2 and 3. This argument is noted but not found to be persuasive.

In response to applicant's argument, the reference of Moring teaches that the orifices in (Figure 3 #28) are connected to the top surface of the collection plate that

Art Unit: 1641

extends through the bottom surface of the plate, which is connected to the interior chamber. Moring et al teaches that the orifices (apertures) are located between each microfiltration well, but the orifices are located below the microfiltration well and therefore below the assay formation areas as recited in amended claim 1 and amended claim 22. Therefore, it is the examiner's position that the reference of Moring still anticipates the instant claims.

10. Applicant argues that Moring cannot make instant claim 1 obvious sine the present invention achieves unexpected results and directs the examiner attention various figures in the instant specification.

Applicant's argument that the instant invention has several advantages that facilitate high-resolution printing and reading of the microarrays is noted, but language of the claims are still anticipated by Moring et al. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Therefore, the structural elements of Moring et al are capable of the providing the same advantages of the instant invention.

Art Unit: 1641

11. Applicant argument that the reference of Mathus neither teaches nor suggests that each orifice is connected directly to both the top surface and the interior chamber , wherein each of the orifices is directly below the assay formation areas.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The reference of Mathus was relied on for its teaching of specific structural limitations. Examiner directs applicant's attention to the above rejection of claims 3 and 16-18. In addition, the reference of Moring anticipates claim 1 and has been addressed in the arguments above

12. Applicant argument that Mohan cannot remedy the defect of Moring because Mohan neither teaches nor suggests orifices that are connected directly to both the top surface of a vacuum fixture and the interior chamber that is connectable to a vacuum source is not found persuasive. Applicant further argues that Mohan does not have a vacuum fixture with a top surface corresponding to the well bottoms or array formation areas. This argument is not found persuasive.

In response to applicant's argument, In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800

Art Unit: 1641

F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Orifices that are connected directly to both the top surface of the interior chamber has been addressed in the arguments above.

The reference of Mohan was relied upon for the teaching of a plurality of caps with inlet and outlet ports, a temperature control element and a vacuum fixture, which are the limitations covered by claims 20-21 and 23-24. Mohan teaches a thermal control block with apertures throughout each one to control the temperature of each reaction vessel.

A capping plate with a plurality of caps that corresponds to an array area containing the reaction vessels. The caps overlies and seals the reaction vessels (column 10, lines 58-67). The microplate assembly of the apparatus has a vacuum fixture on the surface of the interior chamber (Figure 1) for passing fluid through. Therefore, the reference of Mohan et al appears to teach and suggest the limitations of claim 20-21 and 23-24.

13. Applicant argues that Stylli neither teaches or suggests anything related to vacuum fixtures, much less vacuum fixture containing orifices, wherein each orifice is connected directly to both the top surface and the interior chamber, wherein each of the orifices is directly below the assay formation areas. Applicant's arguments are noted but not found to be persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The limitation wherein each orifice connects directly to both the top surface and

Art Unit: 1641

the interior chamber has been addressed in the arguments above for claim 1. Stylli was relied upon for the teaching of a peristaltic pump and a motivation as to why one of ordinary skill in the art would modify the teaching of Moring to include this feature is provided in the rejection above. Therefore all rejections are hereby maintained and made final.

Conclusion

14. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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March 4, 2005



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03/07/05